MEDIUM

- KIs recovered, but not to research
- LI recovered but discarded

CONFIDENTIAL MEDICAL PEER REVIEW

[redacted]

UNOS DONATE LIFE

Member Quality Department: Non-Routine Intake and Triage Form

Staff Completing Intake: [redacted]

Mode of Notification (e.g., member complaint, self-report, observation on site survey): Anonymous

Method of Intake (e.g., phone call, site survey, PSP): Member Reporting Line

Receipt Date (UNOS): 2/24/17 **Receipt Time (UNOS):** 3:06 pm

Receipt Date (MQ): 2/24/17 **Receipt Time (MQ):** 3:06 pm

Intake Date (MQ IH Staff): 2/24/17 **Intake Time (MQ IH Staff):** 3:06 pm

Case Details

Reporting Institution or Individual: Anonymous (MRL)

Subject of Report (Institution or Individual): INOP

Brief Description of Issue: MRL call. [redacted] 2/23/17. Second hand: DCD donor was alive (beating heart) when he was opened; support had been w/d + hr monitored for 5 minutes. HR was again monitored, + death declared 10 minutes later. Recovering surgeon then declared death + proceeded w/ organ recovery.

Section A

1. Does the presenting issue meet any of the criteria listed on Attachment I of this document? ☐ Yes ☑ No
   a. If yes, describe issue below and proceed to question 2.

   _____

   _____

   b. If no, proceed to question 2.
2. Was there direct and specific harm to an identified patient or patients? ☐ Yes ☒ No
   a. If yes, i. Identify the patient or patients: _____

      ii. Specify the harm (e.g., diagnosis, injury, condition): _____

      _____

      iii. When did the harm occur (date, time)? _____

      iv. Then, skip to question 4.

   b. If no, proceed to question 3.
3. Was there high potential for direct and specific harm to an identified patient or patients? ☐ Yes ☑ No
   a. If yes, i. Identify the patient or patients: _____

      ii. Specify the potential harm: _____

      _____

SFC OPTN Hearing
Exhibit K.98

cr m nal acti TBD

e y to yo r M
on of this for [redacted]

es ☐ No

ation to your Manager AND the DEQ Assistant Di ector (Audit & Monitor ng) ☐

and proceed with Routine Investigation Pathway r m ☐

☒

Case Disposition

ake Form mus e completed within 2 hours of receipt despite assigned priority Int

Cate ory Assigned· Initial

Hig (Your manage ust be notified hrough direct communication immed ately.) ☐

Medium (Your man er must be notified within 4 urs of intake.)

Low (Your manager ust review a copy of this form within 1 week of intake.)

f o l ss gn to MEDIUM RIOR d procee to Case D spos t o section of this ☐

Other (Your manager must be notified immediately.)

n ail notifi

5. s there a reasonable concern that t s situation cou d ecu t e near future (i.e , wit IOR TY

Case Referred (See list) Group:

c f yes a s g to HIG PRIOR TY and p oceed o Case D spos t on section of this form

Assigned Case ead:

No If o ass gn o M D UM PR ORITY a oceed to Case D s os t on section of this form

Potential Policy/Bylaw Violations (if applicable) proceed

6. Does e s tua on or issue repre ent a threat to t e ntegr ty r t ust n the OPTN Yes ☐ No

a If yes, report ss e with 4 hours to your Manager th o gh d rect commun cation (phone or face-to-face). Then, proceed to e Case Disposition section of th s form

f no proceed to q est o 7

Section B

7. s here suspic on or a legation v ty? ☐ Ye ☐

a f yes, e ort issue immed a anagem ug to the Case Dispos on secti fo

f o, oceed to question 8

8. he is me we ell ovement ☐ Y

a. f yes sen a e-m

b no, assign LOW R

i When did th s pot

v. T e , o question

b If no pr cee to Sectio B

4. Was there a specific me ber action or inaction that led to the harm or the potential for harm? ☐ Yes ☐ No

a. If yes i. State the act on or nact on (b spec fic)

Management Review (required for all case types):

Management Notified (Date/Time): 2/24 @ 1600 Management Initials: [redacted]

(In manager's absence, notify your Assistant Director.)

Category Assigned:

- ☐ High (AD/Director to notify Executive Director and Assistant Executive Director immediately. Preliminary investigation complete within 24 hours.)
- ☒ Medium (AD/Director to notify Executive Director and Assistant Executive Director within 3 days of receipt of intake.)
- ☐ Low (DEQ A.D. Audit & Monitoring, OPTN Exec. Director and HRSA will be provided a listing of all cases designated "low" priority status on a monthly basis.)
- ☐ Other (Notify executive level UNOS leadership within two business days of intake)

Assistant Director Review (required for high, medium and other):

Assistant Director notified (Date/Time): _____ Assistant Director Initials: _____

Agree with previously assigned category? ☐ Yes ☐ No

If no, reassigned category: ☐ High ☐ Medium ☐ Low ☐ Other

OPTN Executive Director notified (Date/Time): _____

HRSA Notified (Date/Time): _____

☐ Included in monthly HRSA report? Month: _____

☐ Quality Inspection Complete? Date: _____ Initials: _____

v nts that should be re orted to he PTN r wi hin 1 busines da Excludes Saturda Sunday and holidays)

1. Suspected o s gnificant potentia of (non-HIV) i ase trans ission from a donor to a transplant rec pient.
2. Any sanction taken by a sta e medica boar o other professiona body agai st a transplant profess ona "Work ng for an OPTN Membe

Events that should be reported to the OPTN leadership within 24 hours of issue intake:

1. A transplant of the wrong organ into an organ rec pient
2. A near-miss transplant of the wrong organ into an organ recipient
3. A transplant into the wrong organ rec pient
4. A near-miss transplant into the wrong organ recipient
5. A suspected (or confirmed) human immunodeficiency virus (HIV) transmission from a donor (deceased o iving) to a transplant recipient
6. Any complaint, issue, or concern that may pose a serious or time-sensitive threat to public health or patient safety (including failure to provide a safe environment to pat ents), regardless of whether there is a suspected or actual violation of OPTN pol cy or the OPTN f nal rule.
7. A living donor death, regardless of the time period after surgery and regardless of the cause of death
8. Fai ure of a native organ in a living organ donor.
9. Evidence of an attempt to deceive the OPTN or the Department (e.g., falsifying medical records).
10. Use of a device for a condition, diagnosis, or procedure that s contraindicated by the Food and Drug Administration (FDA).
11. Any "Never Event," as included n the Centers for Medicare and Medica d Services' (CMS) pol c es for selected hospital-acquired conditions (HAC's), in an OPTN member hospital that impacts transplant pat ents or living organ donors (ncluding those under evaluation for liv ng organ donation).

With respect to Items 1 and 2, an event should be considered a "near-miss" if the error is not caught before the recipient s brought to the surgery holding area. With respect to Items 1,2,3, or 4, errors that might lead to the transplant of the wrong organ or patient, or near-miss events, may include documentation errors involving dono ABO, donor identification information (ID), ntended recipient name or other ID, packaging or labeling errors (of o gan, issue specimens, blood) involving donor ABO, donor ID, intended recipient name or other ID, and/or the organ type, or an organ that goes to t e wrong d stina on